Health professionals' views about who would benefit from using a closed-loop system: qualitative study

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Running title: Who would benefit from using a closed loop system?

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Conflict of interest

RH reports having received speaker honoraria from Eli Lilly and Novo Nordisk, serving on advisory panel for Eli Lilly and Novo Nordisk, receiving licence fees from BBraun and Medtronic. RH reports patent patents and patent applications. TR reports having received speaker honoraria from Novo Nordisk and consultancy fees from Abbott Diabetes Care. FC reports having received travel expenses and honorarium to attend the Advisory Boards of Medtronic, Dexcom, Ypsomed and Eli Lilly. JL, BK, DR, JMA, NLA, LV, NT and CKB have no conflicts to report.

Novelty statement

- Studies have overwhelmingly focused on users' perspectives and experiences of closed-loop systems.
- This study offers early and important insight into health professionals' views about who would benefit from using a closed-loop system; and, who should be prioritised for access to the technology in routine clinical care.
- Health professionals may hold prejudicial and erroneous views about the kinds of individuals who would most benefit from using a closed-loop system.
- Staff would benefit from training to overcome these prejudicial assumptions and clinical guidelines to support decision-making about allocating and withdrawing closed-loop systems in routine clinical care.

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Abstract

Aims

To explore health professionals' views about who would benefit from using a closed-loop system and who should be prioritised for access to the technology in routine clinical care.

Methods

Health professionals (n=22) delivering the Closed Loop from Onset in type 1 Diabetes (CLOuD) trial were interviewed after they had ≥6 months experience supporting participants using a closed-loop system. Data were analysed thematically.

Results

Interviewees described holding strong assumptions about the kinds of people who would use the technology effectively prior to the trial. Interviewees described changing their views as a result of observing individuals engaging with the closed-loop system in ways they had not anticipated. This included educated, technologically competent individuals who over-interacted with the system in ways which could compromise glycaemic control. Other individuals, who health professionals assumed would struggle to understand and use the technology, were reported to have benefited from it because they stood back and allowed the system to operate without interference. Interviewees concluded that individual, family, and psychological attributes cannot be used as pre-selection criteria and, ideally, all individuals should be given the chance to try the technology. However, it was recognised that clinical guidelines will be needed to inform difficult decisions about treatment allocation (and withdrawal), with young children and infants being considered priority groups.

Conclusions

To ensure fair and equitable access to closed-loop systems, prejudicial assumptions held by health professionals may need to be addressed. To support their decision-making, clinical guidelines need to be made available in a timely manner.

Key words: closed-loop systems, health professionals, qualitative, candidacy

Introduction

A closed-loop system is a rapidly evolving technology for people with type 1 diabetes [1] which has been hailed as a technological revolution [2]. It comprises a real-time continuous glucose monitor (CGM), an insulin pump and an algorithm that translates, in real time, information from the CGM and computes the amount of insulin to be delivered by the pump. These systems require varying levels of user input, with most needing users to count carbohydrates and enter this information before snacking/eating and perform standard pump and CGM related tasks.

The first generation commercially available hybrid closed-loop system, the 670G pump (Medtronic, Northridge, CA, USA), was approved by the US Food and Drug Administration in September 2016, and with CE mark since June 2018, and has been shown to be safe in people with type 1 diabetes aged over 7 years [3]. Other manufacturers are developing next generation closed loop systems including Tandem, Insulet, Tidepool, and Diabeloop [1] whilst people living with diabetes are also developing their own 'do-it-yourself' systems [4].

To support successful rollout in routine clinical care, it is vital to understand how people perceive and engage with this technology. To date, studies have overwhelmingly focused on users and/or family members [5-15]. Health professionals' perspectives have been surprisingly neglected despite their pivotal role as gatekeepers to new diabetes technologies [16]. Indeed, studies have shown that there may be inequitable access to medical devices, such as insulin pumps and CGMs, due to health professionals selecting or filtering potential recipients based on their own preconceptions and clinical judgement [17-19]. As closed-loop systems become more widely available, it is vital that health professionals' perspectives are explored. This includes any preconceptions they might have about who would be the best candidates for the technology [16] and their views about who should be prioritised for access when the technology comes becomes more widely available in routine clinical care.

To address this important gap, we report findings from an interview study with health professionals involved in the Closed Loop from Onset in type 1 Diabetes (CLOuD) trial. This UK-based multi-centre RCT is exploring the benefits of a day-and-night hybrid closed-loop system as compared to a multiple daily injection (MDI) regimen in individuals (aged 10-16

years) newly diagnosed with type 1 diabetes. For details about the closed-loop system used in the first phase of the trial (FlorenceM) see Box 1.

Box 1: The closed-loop system used during the trial

FlorenceM comprised:

- A modified next generation sensor-augmented Medtronic insulin pump 640G (Medtronic Minimed, Northridge, CA, USA) with pump suspend feature
- A Medtronic CGM Transmitter with Guardian 3 sensor
- An Android smartphone containing the Cambridge model predictive algorithm with a propriety translator to allow wireless communication with the insulin pump.

Users are required to: use a standard bolus calculator to deliver meal boluses; change their pump infusion set every 2-3 days; replace the CGM sensor at least every 6 days and calibrate the sensor as required (typically 2-4 times over a 24 hour period); respond to alarms alerting them to high/low blood glucose; ensure that study devices are charged; and, ensure the smartphone is kept in close proximity (5-10 metres) to avoid signal loss with the pump/CGM.

Half the trial recruits were randomized to the closed-loop system with the other half using MDI, with each treatment lasting 24 months during the trial's first phase. For further details about the CLOuD trial see Box 2. Key aims of the health professional interview study were to understand and explore: their views about which kinds of individuals would gain clinical benefit from using a closed-loop system; and, who should be prioritised when closed-loop systems become more widely available within the National Health Service (NHS) and other healthcare settings.

<<Box 2 about here>>

Methods

Qualitative methods are recommended when little is known about the area under investigation as they allow findings to emerge from the data, rather than testing predetermined hypotheses [20,21]. The study was guided by the general principles of Grounded Theory research which advocates a flexible, open-ended approach [22]. 1-1 interviews were undertaken with health professionals using a topic guide, which contained a list of topics to be covered, rather than a set of pre-determined, structured questions. This approach helped ensure the discussion remained relevant to addressing the study aims while affording flexibility for interviewees to raise issues they perceive as salient, including those unforeseen at the study outset. The study was guided by an epistemological position, informed by previous work and the literature on the evaluation of complex (health) interventions [23], which recognises that there may be unanticipated consequences to introducing new diabetes technologies [14,15]. This position partly informed our decision to use topic guides rather than structured interview schedules, to allow (unanticipated) findings to emerge from the data.

Recruitment

Health professionals (physicians, diabetes specialist nurses and research nurses) were recruited from all 7 participating trial centres (see Box 2) after they had ≥6 months experience of delivering the trial and supporting individuals using the closed-loop at their site. Staff were sent written invitations and invited to opt-in, with recruitment materials making it clear that the interviews were being conducted by an independent research team. Recruitment continued until data saturation was reached (i.e. until no new findings were identified in new data collected) and there was good representation of different staff from across all sites.

Data collection and analysis

Interviews were undertaken by BK, an experienced, non-clinical qualitative researcher, between August 2018 and June 2019. The interview topic guide was informed by literature reviews, inputs from clinical coinvestigators and revised in light of emerging findings (based

on an initial review of the first five interviews – see Box 3). Key areas explored relevant to the reporting in this article are described in Box 3. Interviews averaged 70 minutes, were digitally audio-recorded and transcribed in full.

<<Box 3 about here>>

To promote rigor two experienced, non-clinical qualitative researchers (BK and JL) undertook data analysis. Once all interviews had been completed, data were analysed thematically using the method of constant comparison [22]. Individual interviews were read through repeatedly (data immersion) before being cross-compared to identify issues which cut across different accounts (themes). JL and BK undertook separate analyses and wrote separate reports before meeting (on three occasions) to discuss their interpretations and reach agreement on key themes. As there was striking consistency in staff accounts, there was strong agreement about what the main themes were. A coding frame was developed that captured these five themes: "the closed-loop system: less work, but still work", "preconceptions about candidacy", "revisiting candidacy in light of trial experiences", "use of the closed-loop system in routine clinical care"; and, "who should be given priority and clinical guidelines". An additional theme identified during data analysis – "unanticipated issues" – cut across the other themes; hence, it is not presented separately in data reporting below. The qualitative analysis software package NVivo10 (QSR International, Doncaster, Australia) was used to facilitate data coding and retrieval. Coded datasets were subjected to further analysis to allow more fine-grained interpretations of the data and identify illustrative quotations.

Ethics approval was granted by the Usher Research Ethics Group (UREG), University of Edinburgh (approval date: 08 February 2018). To safeguard anonymity, unique identifiers are used below (e.g. D, refers to a doctor, N refers to a diabetes specialist nurse and RN refers to a research nurse).

Results

The sample comprised 22 health professionals (7 doctors, 9 diabetes specialist nurses, and 6 research nurses). See Table 1 for more details.

<<Table 1 about here>>

We begin by describing interviewees' perceptions and understandings of the closed-loop system to set the context for understanding their (pre-trial) preconceptions about who would be the best candidates for this technology. We then consider how, and why, their opinions changed as a result of observing individuals using the system in ways they had not expected during the trial. We then explore their opinions about who should be prioritised in routine clinical care and what sorts of guidelines will be needed. As all the main themes cut across the dataset, our reporting has not been separated out according to health professionals' individual characteristics.

Perceptions and understanding of the closed-loop system: Less work; but still work

While interviewees perceived the closed-loop system as requiring "less brain power moment-to-moment than having to think about it all for yourself" (N4), they also emphasised that: "they're definitely not fit and forget systems. You can't just say to someone, okay, here's your pump, here's your sensor, go away, it does everything for you" (N5). Indeed, in order to benefit from the system, interviewees noted how essential tasks, which required time and effort, needed to be undertaken:

> "You still need to be doing what the technology needs you to do. You need to be doing the calibrations at the right time and you need to be changing your cannulas frequently." (RN3)

Interviewees also emphasised the importance of family involvement to help ensure the young person kept the system on and in range of other devices, was regularly bolusing for meals, and offer encouragement and practical support if necessary:

> "we really say to the parents, 'It is important that you're there for them, even if they're at the older end of you know, the 16, 17 [year olds], they're still not gonna want to have the diabetes, it's not gonna be at the top of their list of priorities… So it's important that you're there to kind of supervise and make sure that they are doing

what they need to be doing to stay safe and well." (N8)

Pre-trial notions of candidacy

For the above reasons, interviewees noted how, prior to the trial, they had assumed that some individuals and families would better placed than others to use the closed-loop system effectively. Specifically, interviewees suggested that close-knit families, where the parents lived together rather than in separate households and where they had close and supportive relationships with the young person would be the best candidates for the technology:

> "because some parents, because they're busy, they've got other lives, they don't see it as their problem … [whereas] children and young people who get lots of support and help from families do very well." (D1)

Interviewees also emphasised the importance of users having a good understanding of the system and how it worked to ensure it was used safely and effectively:

> "If you don't really fundamentally understand what the closed-loop does, rather than being just sort of, "yeah it does it all anyway, you don't need to do very much" then it's actually quite dangerous to put somebody on a closed-loop." (D3)

For this reason, interviewees also noted how, prior to the trial, they had assumed that "somebody who is well educated, involved in technology and keen to understand would be the best person" (D3) and, conversely, that individuals would be less likely to be good candidates for the technology if they did not possess these attributes: "I know that sounds really harsh, but you have to have a certain academic understanding in order to be able to cope" (RN5).

Revisiting candidacy in light of trial experiences

Interviewees also noted how, as a result of working on the trial, their preconceptions about candidacy had been challenged. As these individuals further described, this change in perspective had resulted from access to the technology being determined by the trial's

inclusion/exclusion criteria and a randomization process rather than their own clinical judgement and prior (albeit limited) knowledge of the young person and their family. As a consequence, they had been exposed to individuals using the technology who might not have been encouraged to use the system had it been available in routine clinical care.

When they reflected on how their preconceptions had been challenged, interviewees from across the sites highlighted examples where well-educated individuals, including some who had technical or medical knowledge, had over-interacted with the system with a resultant detrimental impact on blood glucose control:

> "We have one patient whose mother comes from a slightly medical background and from the moment the child went on to the closed-loop system, micromanaged. So was constantly looking at it [closed-loop] and putting [basal] rates up and pushing rates down and bolusing … When people do go in and fiddle a lot, it takes longer for [closed-loop] to learn what the basics need to be, and that causes more problems." (D6)

Conversely, some, including N6 noted how, "your ordinary families that you might not consider quite as intelligent, that are just happy to sort of follow the basic rules, are the ones that will actually do better on it… Because they let it [closed-loop system] get on and do its thing." A similar observation was made by RN3 who pointed out that:

> "often some of the families that people don't think would understand it so well maybe are the ones that follow [it] better, because if you say, 'These are the steps that you need to do for the system to work', they generally will follow the steps. Whereas I've found in general- very, very broadly speaking, those that are a little bit more academically minded, maybe want to fiddle more, which doesn't necessarily help."

Others highlighted the difficulties of gauging family dynamics and, hence, determining whether the young person would receive the support needed to use the technology effectively:

> "sometimes– it sounds terrible – but you expect a certain family to not be able to take to things and maybe- might struggle with the technology. And you're quite shocked that they do really well … I think because you only see a snapshot of a family when they come in…So obviously that's not the whole picture to what's going on at home… there's a lot more love and support… than you can actually see." (RN1)

Even when interviewees felt they had gauged family dynamics and/or individual motivation correctly, some observed how using the technology could act as a tipping-point and lead to increased engagement with diabetes self-management: "sometimes you can have ones that are non-compliant, and you give them something like this and they could revert beautifully." (RN2)

As a consequence, interviewees concluded that, "you can't really judge based on any of the usual factors how well a person is going to do, like sort of social factors, intelligence and all of those things." (N6)

Views about the use of closed-loop systems in routine clinical care

Given the difficulties of predicting who would make effective use of the closed-loop system, interviewees conveyed a very strong and consistent view that, in routine clinical care, potential recipients should not be selected or filtered out on the basis of their own clinical judgement: "everybody would deserve it. You know, give them a chance with it. (N2)

However, given the insights gained from working on the trial, interviewees also recommended that there should be a probationary period with clear rules in place for taking the system off those who neglect key tasks and, hence, do not gain better (and possibly have worse) glycaemic control than they would from using less costly (e.g., MDI) regimens.

> "But obviously if they're not using it effectively then it's not a cost-effective way of delivering the insulin... So… then you'd have to have those conversations then with them, and say, you know, give them a chance to turn it round. And if they don't, then pull it." (N2)

In light of their experiences of observing participants using a closed-loop system for durations of ≥2 years, some interviewees also highlighted the need for longer-term review to ensure individuals continued to use the technology safely and effectively: "it should be offered on a trial basis and it should be reviewed and, I don't know, yearly for four years or whatever" (D3). This, as some noted, was because an unanticipated consequence of using the closed-loop system was that it could lead to self-management tasks, such as bolusing for meals, being relaxed over time:

> "It's kind of a two-edged sword really, because in one way that does keep them safer, but if they realise that actually, you know, it's fine even if I don't give a bolus after I've eaten something or I can get away with snacking and my blood sugar will still usually be alright in the end… then, you know, they can get quite blasé." (D1)

Staff views about who should be given priority and the need for clinical guidelines

Interviewees described recognising that within a financially constrained setting such as the NHS, difficult decisions would need to be made about who should be prioritised for a closed-loop system and that clinical guidelines would be essential: "it's just so limiting giving priority, because everyone should have it. But then when you go and speak to the money people you have to give priority" (D4); "we are juggling with budgets, and it's not the NHS's fault that they can't provide all these things for people" (N6).

However, when asked which categories of individuals should be prioritised, many were reluctant to be drawn on this issue: "oh that's a horrible question" (N3); "I don't want to be involved in decisions about it" (D5). For some, teenagers were considered a priority group. This was not only because "you've got hormones kicking in and the insulin requirements change all the time" (N9), but also because of social factors which make diabetes particularly burdensome:

> "I do think that age group that we've targeted for the study is a good age group to have it, because they often struggle the most with kind of coming to terms with it [diabetes] and having to do the injections and all the testing." (N9)

Indeed, it was noted that, even if diabetes was neglected in this age group, individuals could still gain greater glycaemic benefit from using a closed-loop than another regimen because, "it does probably keep them safer… If they've missed a bolus even, if they haven't done what they're supposed to do, the closed-loop does react and corrects and gives more insulin." (N9)

Most, however, emphasised that young children and infants should be prioritised because of the unpredictability of eating in this age group, the tiny and variable amounts of insulin required and, crucially, because these individuals would have diabetes for the longest and, hence, would benefit most from the glycaemic control offered by the closed-loop system:

> "everything about being a toddler: the blood glucose control, the erratic nature of it, the fact that you can't, you know, issue instructions to a two-year-old to eat their dinner after you've injected insulin, and so on and so forth." (N6)

Some, however, also noted that, to be a viable option in this age group, an adapted system would be needed with the algorithm integrated into the pump or another easy to transport device, such as a smart watch.

Amongst adults, interviewees generally saw the priority groups as being those already meeting clinical (e.g. National Institute of Clinical Excellence (NICE)) criteria for insulin pump therapy. As well as pregnant women these included:

> "people whose hypos are a problem, they've got some quite good set criteria around that, so I think that'll be the first group that gets it. And then I think if I had to give another group on top of that, it would be those that have more erratic control, really difficult to manage diabetes." (N4)

However, some conveyed very ambivalent views about current pump criteria being extended to closed-loop systems, given the life-changing potential of the technology and its ability to offer better glycaemic control in all groups: "If (someone) is looking after their diabetes very well, why should they be penalised because they're doing a good job." (D2)

Discussion

This study offers early and important insight into health professionals' perceptions of, and views about, the types of individuals who would be likely to gain greatest clinical benefit from using a closed-loop system. For the benefits of the closed-loop system to be fully realised, interviewees noted that essential tasks, which required time and effort, needed to be undertaken and, hence, that not all individuals would use the technology optimally. For this reason, interviewees also described how, in advance of the trial, they had held strong assumptions about the kinds of individuals (and families) who would have the motivation and ability to use the technology effectively. Such views, as interviewees further noted, were challenged by observing individuals using the technology in ways they had not anticipated. Interviewees thus concluded that individual, family, and psychological attributes (e.g. motivation) cannot be used to predict how people will engage with the technology. Hence, they suggested that, ideally, all individuals should be given a chance to try a closed-loop system. However, it was also recognised that clinical guidelines would be needed to inform potentially difficult decisions about who should be prioritised in settings such as the NHS where budgetary constraints may limit access to new diabetes technologies [24,25].

In keeping with others' concerns [16], our findings suggest there is a danger that, in routine clinical situations, health professionals' own attitudes and biases could result in some individuals who might benefit from closed-loop technology not being given the opportunity to use it. Informal rationing of diabetes technologies has already been reported by others [17,18]. In an interview study with health professionals involved in insulin pump referrals, it was found that these individuals exercised personal judgements about whether individuals possessed the psychological and technological attributes needed to use pump technology effectively. It was only after these health professionals were involved in a clinical trial (comparing pumps with MDI regimens [26]) that they were forced out of this state of clinical inertia [17], by virtue of observing individuals benefitting from an insulin pump who would not have been moved onto this technology in routine clinical care [17]. Like the health professionals involved in the insulin pump trial, health professionals in the current study

also appeared to change their perceptions of candidacy as a result of being exposed to individuals who might not have been encouraged to use the technology had it been available in routine clinical care. Hence, to ensure fair and equitable access to closed-loop systems, it is vital that health professionals are encouraged to explore any prejudicial assumptions they may have, and given support to overcome these. To this end, case studies of individuals benefiting from the technology who do not conform to health professionals' preconceptions could be used as part of their training.

While health professionals supported mainstreaming the technology, they recognised that difficult decisions would need to be made about who should actually get access to it. To this end, most emphasised the need for clinical guidelines to be made available in a timely manner. Most also indicated being broadly supportive of current eligibility criteria for insulin pump referrals [27] being extended to closed-loop technology. In addition, interviewees emphasised the need for clear guidance to be put in place for removing closed-loop systems from those who do not use them in clinically and cost-effective ways. This, as interviewees noted, potentially included individuals who initially use the technology effectively, but whose engagement and behaviour might change over time. Indeed, in keeping with users' accounts [14], interviewees noted how the system's ability to partly compensate for behaviour lapses, such as missed boluses, might lead to increased neglect of self-management over time. These findings suggest that regular, ongoing review of individuals using a closed-loop system will be essential, in line with recommendations for those using other diabetes technologies [25]. Even if clear guidance is put in place for when to remove a closed-loop system, this may still be very challenging task [28], and effective team working may be vital [29].

In taking our findings and recommendations forward, it needs to be considered that the health professionals were involved in a clinical trial and, hence, may already have been technology enthusiasts. In addition, most specialised in paediatric diabetes care; this might partly explain why they were keen for younger age groups to be prioritised for access to the technology. It should be also noted that the young people involved in the trial were newly diagnosed and this might affect the study's generalisability. However, this did also mean that health professionals did not have extensive knowledge of these individuals and their

family dynamics prior to the trial that might have deterred them from recruiting individuals who did not meet their (pre-trial) assumptions about candidacy. Future work could consider the perspectives of health professionals working in adult diabetes care and in settings where healthcare is privatised and, hence, different barriers to accessing the technology are likely to exist [18,30]. Health professionals' views about providing access to different and newer iterations of closed-loop technology could also be considered.

The closed-loop system used during the trial was a prototype. Hence, it is likely that some of the barriers to use highlighted by interviewees and reported by users [7,8,13] will be ameliorated by future developments in the technology. This includes the introduction of calibration-free CGM sensors, the use of patch pumps with integrated algorithms, the integration of the algorithm onto a smartphone or smartwatch, and improvements in user experience to minimise unnecessary alerts and device burden [1,2]. Hence, in the future, it is likely that increasing numbers of individuals will want and benefit from this technology, resulting in even more difficult decisions needing to be made about who should get access to it.

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Box 2: Details about the CLouD trial

The CLOuD trial was designed to assess whether closed-loop technology can preserve the function of beta-cells in young people who have recently been diagnosed with type 1 diabetes better than standard treatment (MDI) (see: https://clinicaltrials.gov/ct2/show/NCT02871089).

To be eligible for the trial, individuals had to: have received a diagnosis of type 1 diabetes within the previous 21 days; be aged at least 10 years and not older than 16.9 years; be willing to perform capillary blood glucose monitoring and take at least 4 blood glucose measurements each day; wear study equipment (glucose sensor and closed-loop system); and, upload pump and CGM data at regular intervals.

Following randomisation, participants in the closed loop group received training sessions to cover key aspects of insulin pump use and CGM, prior to starting closed loop insulin delivery. Once competent in the use of the study pump and CGM system, participants received training required for safe and effective use of the closed loop system. During a 2-4 hour session participants operated the system under the supervision of the clinical team. Competency on the use of closed loop system was evaluated. Thereafter, participants were expected to use closed loop for 24 months without supervision or remote monitoring.

During the two years of the intervention, participants were seen in the clinic at three-month intervals. All participants continued to be seen by their clinical team at frequencies as appropriate in line with usual clinical practice. All study visits were scheduled in addition to routine visits. All participants were provided with a 24-hour helpline to contact the study team in the event of study-related issues.

The trial was conducted in 7 UK-based NHS sites with Diabetes Paediatric Clinics: Addenbrooke's Hospital, Cambridge; Leeds Children's Hospital, Leeds; Alder Hey Children's Hospital, Liverpool; Nottingham Children's Hospital, Nottingham; Oxford Children's Hospital, Oxford; Southampton Children's Hospital, Southampton; and, Royal Hospital for Children and Young People, Edinburgh. All sites were experienced in the use of insulin pumps and CGM devices but their broader experience with closed-loop systems was limited at the time when the research was conducted. All site staff delivering the trial were trained on the closed-loop system and its components and completed competency checklists. Most health professionals (except research nurses) who delivered the trial also provided participants with routine clinical care.

Box 3: Key areas explored in the interviews

- Clinical background, training and experience; previous involvement (if any) in trials of closed-loop technology; experiences of recruiting into and delivering the CLOuD trial.

- Perceptions and understanding of the closed-loop, including how the system works and how individuals need to use it in order to gain optimal clinical benefit.

- Role of family members/others in supporting individuals to use the technology and undertake key diabetes self-management tasks e.g. blood glucose self-monitoring, counting carbohydrates et cetera.

- Barriers and facilitators to diabetes self-management within the age group involved in the trial; impact of closed-loop system on diabetes self-management practices in this age group.

- Perceived benefits and drawbacks of using closed-loop technology as compared to other regimens (e.g. pump and MDI).

- Initial (pre-trial) views about which types of individuals would (and would not) gain clinical benefit from using a closed-loop, and why.*

- Current (i.e., at the time of the interview) views about who are the best candidates for the closed-loop;

    - if these views have changed from those pre-trial, why? *

- Perceived impact of trial participation on health professionals' clinical practice when closed-loop technology becomes more widely available in the NHS.

- Views about who should be prioritised for access to closed-loop technology; content and use of future clinical guidelines.**

* topic/probe added in light of an initial review of the interviews and interviewees describing revising their opinions about closed-loop candidacy as a result of trial participation

** topic added in light of interviewees suggesting that, in routine clinical care, everyone should be given a chance to try the technology; hence it was important to explore views about how this access could be managed.

Table 1: Participant characteristics

	N	**%**
CLOuD sites (n=7)		
Total number of interviewees	22	
Interviewees per site - range (mode)	1-5 (4)	
Role		
Diabetes Consultants	7	32
Diabetes Nurses	9	41
Research Nurses	6	27
Number of staff with previous closed-loop experience	5	23
Years of diabetes experience		
<5	6	27.3
5-10	5	22.7
>10	11	50.0